Applicants acknowledge that the Office Action has made the restriction requirement final.

Applicants respectfully maintain its traversal for the reasons of record.

The Office Action provisionally rejects claims 1-15 under the 35 U.S.C. 101 as being unpatentable over claims 1-3 and 5-16 of co-pending Application No. 09/455,544. In response, Applicants respectfully acknowledge the need to cancel claims or to file a Terminal Disclaimer if ultimately allowed claims in the above-captioned patent application improperly conflict with, or extend the patent right in, the copending patent application. Applicants respectfully request that this rejection be held in abeyance until allowable subject matter is indicated. If ultimately deemed necessary, then Applicants will file an appropriate Terminal Disclaimer at that time.

The Office Action rejects claim 1 under 35 U.S.C. 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action, at pages 4 and 5, states:

Claim 1 recites the term 'transduction modulator.' It is unclear exactly what 'transduction modulators' are because they are not well defined in the specification. The Specification teaches that 'transduction modulators' can be selected phytochemicals such as forskolin, or from proteins such as PKC. It is known that forskolin is a cAMP activator, however, it is not thought that forskolin is known as 'transduction modulators.' The term 'transduction modulator' is further indefinite in that if 'transduction modulators' are any compound which would have an effect on the cAMP signal transduction pathway, then there would be a countless number of compounds which would in fact perform However, the mechanisms of each and every 'transduction modulator' is not known, and therefore, the term 'transduction modulator' is' not clearly delineated in the claim. Clarification is necessary.

Claim 3 recites 'cAMP/cAMP-dependent protein kinase.' The Examiner believes that this is a complex, but is not sure. Clarification is requested.

Applicants respectfully submit that originally-filed claim is clear and definite and would be readily understood by the one of skill in the art. However, solely in an effort to advance prosecution, Applicants have amended claim 1 to overcome the rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action rejects claims 1-14 under 35 U.S.C. 112, first paragraph, allegedly because the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with the claims. The Office Action, at pages 5-11, states:

...the specification, while being enabling for a composition comprising a plant essential oil compound which is known in the art for treating cancer or abnormal cell proliferation, such as monoterpines (eugenol), along with growth factor receptor inhibitors such as FGF inhibitor, does not reasonably provide enablement for any plant oil compound or any plant oil compound specifically recited in the Markush Group of plant essential oil compounds in Claim 2, in combination with a signal transduction modulator such as cANW/cANW-dependent [sic] protein kinase, tyrosine kinase, calcium phospholipid-dependent protein kinase, activated protein kinase family members calcium-calmodulin-dependent protein kinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

...Plant essential oil compounds such as monoterpenes are known in the art to exhibit cell growth inhibition. However, it would be highly unpredictable to ascertain whether any plant essential oil compound (Claim 1), or any plant essential oil compound found in the Markush Group of Claim 2 would effectively inhibit abnormal cell proliferation. The state of the art regarding cancer treatments is unpredictable. As of yet, there is no cure for cancer despite rigorous pharmaceutical research and experimentation. Bally et al. (US 5,595,756) stated that Despite enormous investments of financial and human resources, no cure exists for a variety of diseases. For example, cancer remains one of the major causes of death. A number of bioactive agents have been found, to varying

degrees, to be effective against tumor cells. However, the clinical use of such antitumor agents has been highly compromised because of treatment-limiting toxicities" (Col. 1 lines 17-24).

Thus, In order to ascertain the effectiveness of a compound in the treatment for abnormal cell proliferation, one would need to provide substantial evidence of such. The Instant specification lacks critical guidance with respect to any plant, essential oil compounds, besides the ones clearly displayed in the Specification (thymol, isoeugenol, eugenol and cinnamic aldehyde) and those already known in the art (monoterpenes) which would function commensurate in scope with the claimed invention. alcohol for example, which is found in the Markush group in Claim 3, is a well known alcohol which is purified from plant essential oils. Benzyl alcohol is not a monoterpene. Although benzyl alcohol is known to be used in the art as a carrier for pharmaceutical compositions, teachings where benzyl alcohol inhibits cell proliferation could not be found in the art. Furthermore, as evidenced by the data provided in the Instant specification itself, plant essential oils are unpredictable with regard to inhibition of cell proliferation (Figure 3).

Absent such critical guidance with respect to any plant oil essential compounds, or any of the plant essential oil compounds in Claim 3 besides those shown in the specification and/or known in the prior art for effectively inhibiting cell proliferation, one of skill in the art would necessarily be required to put forth a substantial inventive contribution in order to ascertain whether or not all of the compounds in the Markush group of Claim 3, as well as any other plant essential oil compounds, would function as effectively as those plant essential oils already known, or displayed in the Instant specification to have a beneficial effect with regard to cancer or tumor inhibition.

Applicants respectfully traverse this rejection.

The Federal Circuit has held that a patent need not teach, and preferably omits, what is well known in the art. See In re Buchner, 18 U.S.P.Q.2d 1331 (Fed. Cir. 1991). The test for enablement is whether one of ordinary skill in the art can make or use the claimed invention without undue experimentation in light of the application disclosure coupled with the information known in the

art. United States v. Telectronics, Inc., 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). In describing the claimed invention, the Applicants are not required to explain every detail since they are speaking to those of ordinary skill in the art. In re Howarth, 210 U.S.P.Q. 690, 691 (CCPA 1981). Thus, a patent may be enabling even though some experimentation is necessary, as long as the amount of the experimentation is not unduly extensive. Utter v. Hiraga, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988).

Moreover, a rejection based on a lack of enablement cannot be maintained solely on the basis that the number of claimed compounds exceeds those specifically disclosed in the specification or that an inadequate number of specific examples is presented. There is no magical relationship between the number of representative examples and the breadth of the claims. In fact, no working examples are necessary, although the absence of examples could be a factor in determining undue experimentation. *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970). When a broad term is supported by the specification, an Applicant should not be denied the use of the term merely because it is broad. *In re Grier*, 144 U.S.P.Q. 654 (CCPA 1965). As explained by the Court of Customs and Patent Appeals:

Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would

have to be limited to those embodiments which are expressly disclosed.

In re Angstadt, 190 U.S.P.Q. 214, 218 (CCPA 1976). In line with this statement, the Court of Customs and Patent Appeals in In re Johnson and Farnham, 194 U.S.P.Q. 187, 195 (CCPA 1977), citing In re Goffe, 191 U.S.P.Q. 429, 431 (CCPA 1976), exemplified:

[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

Applicants respectfully point out that the asserted utility of the claimed invention is not preventing or curing cancer. Rather, the specification states that the presently claimed invention provide therapy or treatment for cancer, in particular, soft tissue cancers. Indeed, the examples in the specification exemplify preferred embodiments of the claimed invention. The specification specifically teaches that the claimed compositions are effective anticancer therapies that would readily be appreciated by those skilled in the art. Applicants have validated this presumption by conducting *in vitro* assays to measure the effects of the disclosed compositions. Moreover, the present specification is not a "hunting license", as inferred by the Office Action. If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. § 112, is satisfied. *In re Brana*, 51 F.2d 1560, 1566, 34 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1993). *In re Johnson*, 282 F.2d 370, 373, 127 U.S.P.Q. 216, 219 (C.C.P.A. 1960); and *In re Hitchings*, 342 F.2d 80, 87, 144 U.S.P.Q. 637, 643 (C.C.P.A. 1965). Applicants respectfully submit that the present specification provides sufficient examples of preferred compositions that have been

tested for therapeutic activity in several different kinds of *in vitro* assays, which are reasonably predictive of therapeutic activity. The exemplified assays, however, are not proof of safety, efficacy, toxicity, routes of administration and dosage of the recited compounds; the patent laws do not require them to be such indicators. Such issues are readily determinable in the art via routine, although possibly extensive, experimentation and are not probative in determining whether the claimed invention is enabled by the originally-filed specification. Indeed, such issues are addressed by other governmental agencies. In short, Applicants provide specific and useful teachings with enough detail to enable one skill in the art to make and used the claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of the non-enablement rejection under 35 U.S.C. § 112, first paragraph.

The Office Action rejects claims 1-6 under 35 U.S.C.102(b) as being anticipated by Marty. The Office Action at page 11 states: "Marty (GB 2,151,924 A) disclosed a composition which contained primrose oil along with cyclic AMP (a signal transduction modulator) (Please see Claims 1-9). Primrose oil would have inherently contained 'plant essential oil compounds.' The language 'for the prevention or treatment of soft tissue cancer' is merely an intended use for a known composition which does not materially change the composition." Applicants respectfully traverse this rejection.

The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under any statutory provision always rests on the PTO. *In re Mayne*, 104 F.3d 1339, 41 U.S.P.Q.2d 1451 (Fed. Cir. 1997); *In re Oetiker*, 977 F. 2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). Applicants respectfully submit that the Office Action has not discharged this initial burden. The factual determination of lack of novelty under 35 U.S.C. § 102 requires the identical

disclosure in a single reference of each element of a claimed invention. The Kegel Co. v. AMF Bowling, 127 F.3d 1420, 44 U.S.P.Q.2d 1123 (Fed. Cir. 1997); Gechter v. Davidson, 116 F.3d 1454, 43 U.S.P.Q.2d 1030 (Fed. Cir., 1997). In rejecting a claim under 35 U.S.C. §102, the PTO is required to identify wherein a particular reference identically discloses each feature of the claimed invention. In re Rijckaert, 9 F.3d 1531, 28 U.S.P.Q.2d 1955 (Fed. Cir. 1993); Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 U.S.P.Q. 481 (Fed. Cir. 1984). There are significant differences between the presently claimed invention and the cited references. To whatever extent the imposed rejections are predicated upon the doctrine of inherency, such reliance is totally misplaced. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. See Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1269, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991); Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159, 47 U.S.P.Q.2d 1829, 1834 (Fed. Cir. 1998) ("In order for a disclosure to be inherent . . . the missing descriptive matter must necessarily be present in the . . . application's specification such that one skilled in the art would recognize such a disclosure."). Inherency is not a matter of hindsight based on the applicant's disclosure: the missing claim elements must necessarily be present in the prior art. Since the claimed invention is not described in a single prior art reference, it is not "anticipated."

As acknowledged in the Office Action, Marty merely discloses the use of primrose oil. The Office Action nowhere shows that primrose oil contains the compounds recited in claim 1. Indeed, Marty is conspicuously mute as to the fundamental concept of treating or preventing cancer using anything but primrose oil. This fundamental difference alone between the claimed invention and

the cited references is sufficient to undermine the factual determination of lack of novelty under 35 U.S.C. §102. See Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986). It is well settled that the doctrine of inherency requires both certainty and art recognition. In re Paulsen, 30 F.3d 1475, 31 U.S.P.Q.2d 167 (Fed. Cir. 1994); Electro Medical Systems S.A. v. Cooper, Life Sciences, Inc. 34 F.3d 1048, 32 U.S.P.Q.2d 1017 (Fed. Cir. 1994). It is not apparent, and the PTO has not identified, wherein the cited reference lies a disclosure of the activity of the presently claimed composition. The requirement for certainty coupled with art recognition is not satisfied by Marty. Thus, there is no basis upon which to predicate the determination that the claimed invention is anticipated by Marty. Applicants, therefore, respectfully submit that the imposed rejection of claims 1-5 under 35 U.S.C. § 102(b) predicated upon the cited references is not factually or legally viable to shift the burden of proof and, hence, solicit reconsideration and withdrawal thereof.

The Office Action rejects claims 1-8 and 10-14 under 35 U.S.C. 103 as being obvious over Bernfeld et al. (US 6,028,061) taken with Yakota et al. (1986) and further in view of (Bardon et al. 1998). The Office Action at pages 11-14 states:

Claims 1-8 and 10-14 are drawn to a composition comprising a plant essential oil compound and a signal transduction modulator such as growth factor receptor inhibitors. Claims are further drawn to specific plant essential oil compounds such as isoeuegenol and carvacrol for example.

Bernfield et al. (US 6,028,061) taught that inhibition of the angiogenesis promoting agent fibroblast growth factor (FGF) with inhibitors such as glycosaminoglycan decreased angiogenesis (cell proliferation) which consequently could have been used in tumor growth inhibition (Col. 2, lines 58-65 and Col. 3, lines 1-6).

Yokota et al. (1986) disclosed that eugenol was useful in inhibiting cell proliferation when administered to mutagenically exposed rats (See Table 2).

Bardon et al. (1998) taught that monoterpenes inhibited the growth of breast cancer cell proliferation (See Figures 1-4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is 1 known in the art to inhibit abnormal cell proliferation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

...Because all of the compounds in claims 6-8 and 10-14 are monoterpenes, one of ordinary skill in the art would have had a reasonable expectation that they would have functioned similarly to the monoterpenes disclosed by Bardon et al. Because monoterpenes were known in the art for inhibiting abnormal cell proliferation, one would have been motivated to have added monoterpenes such as thyrnol or carvacrol into a pharmaceutical preparation in order to beneficially treat abnormal cell proliferation.

Applicants respectfully traverse this rejection.

The Federal Circuit in In re Dembiczak noted that:

Measuring a claimed invention against the standard established by section 103 requires the off-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). The Patent Office "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783

(Fed. Cir. 1988). Rather, in making a rejection under 35 U.S.C. 103(a), the Patent Office must show a teaching or motivation to combine the cited prior art references. See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." Id. "When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." In re Rouffel, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) (citing In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987)). "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). Although the suggestion to combine references may flow from the nature of the problem, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), "[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness," Monarch Knitting Mach. Corp. v. Sulzer Morat Gmbh, 139 F.3d 877, 880, 45 USPQ2d 1977, 1981 (Fed. Cir. 1998). Therefore, "[w]hen determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." In re Beattie, 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (quoting Lindemann, 730 F.2d at 1462, 221 USPQ at 488).

Applicants respectfully submit that the Patent Office has used the rejected claims as a blueprint with the deficient Bernfield reference and looked to other cited prior art references for clements present in the claimed invention but missing from Bernfield. The Office Action does not discuss any specific evidence of motivation to combine, but only makes conclusory statements. "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. The Office Action provides no support for its broad conclusory statement that the subject matter of the rejected claims was known in the art. Nor does the Office Action provide support for its implicit finding that it would be obvious to one of ordinary skill in the art to combine the teachings of the cited references. In fact, nowhere does the Office Action particularly identify any suggestion, teaching, or motivation to combine the cited references, let alone any cogent technical reasoning, to achieve the claimed invention. The absence of a convincing discussion of the specific sources of the motivation to combine the cited prior art references is a critical omission in the pending obviouness rejection.

Moreover, the Federal Circuit has held that "[t]he suggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." WMS Gaming, Inc. v. International Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). However, there still must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F.3d at 1357, 47 USPQ2d at 1456; see also In re Werner Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d

1313, 1317 (Fed. Cir. 2000) ("[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."). Here, there was no such evidence presented.

For instance, Bernfield merely discloses that inhibition of the angiogenesis promoting agent fibroblast growth factor (FGF) was accomplished with inhibitors such as glycosaminoglycan. Yokota fails to remedy the deficiencies of Bernfield. Yokota merely disclosed that eugenol *alone* was useful in inhibiting cell proliferation when administered to mutagenically exposed rats. Yokota nowhere discloses or suggest the use of eugenol with a signal transduction modulator. Bardon fails to remedy the deficiencies of either Bernfield or Yokota. In particular, Bardon merely discloses that certain monoterpenes inhibited the growth of breast cancer cell proliferation. Bardon, however, nowhere discloses or suggests the features required by the presently claimed invention. Applicants respectfully submit that alone or improperly combined, the applied references would not have taught, suggested or provided any motivation to one ordinary skill in the art to reach the claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 103.

In summary, the present invention stems from the recognition that compounds of naturally occurring plant essential oils unexpectedly exhibit anticancer activity, especially when mixed in various signal transduction modulators. One having ordinary skill in the art would have no difficulty practicing the claimed invention, armed with the supporting specification, without undue experimentation. None of the applied references, taken singly or in combination, disclose.

suggest or inherently involve the herbicidal activity exemplified by the claimed invention.

Applicant, therefore, respectfully submits that the imposed rejections have been overcome and, hence, solicit withdrawal thereof.

Please grant any extension of time necessary for entry of this communication. Please charge any deficient fees, or credit any overpayment of fees, to Deposit Account No. 50-0417. A duplicate copy of this communication is attached.

Respectfully submitted,

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WDC99 469688-1.045112.0045

Attorney Docket No. 45112-045

Application Serial No. 09/455,543

## **ATTACHMENT**

"Version With Markings To Show Changes Made."

## IN THE CLAIMS

- 1. [AMENDED] A pharmaceutical composition for the prevention or treatment of soft tissue cancer in mammals comprising a pharmaceutically effective amount of at least one plant essential oil compound selected from the group consisting of aldehyde C16 (pure), amyl cinnamic aldehyde, amyl salicylate, anisic aldehyde, benzyl alcohol, benzyl acetate, cinnamaldehyde, cinnamic alcohol, d-terpineol, carvacrol, carveol, citral, citronellal, citronellol, p-cymene diethyl phthalate, dimethyl salicylate, dipropylene glycol. eucalyptol (cineole), eugenol, iso-eugenol, galaxolide, geraniol, guaiacol, ionone, d-limonene, menthol, methyl anthranilate, methyl ionone, methyl salicylate, α-phellandrene, pennyroyal oil perillaldehyde 1- or 2-phenyl ethyl alcohol, 1- or 2-phenyl ethyl propionate, piperonal, piperonyl acetate piperonyl alcohol, D-pulegone, terpinen-4ol, terpinyl acetate, 4-tert butylcyclohexyl acetate, thyme oil, thymol, metabolites of transanethole, vanillin, and ethyl vanillin and at least one signal transduction modulator selected from the group consisting of cyclic adenosine monophosphate (cAMP), cAMPdependent protein kinase, tyrosine kinase, calcium phospholipid-dependent protein kinase (PKC), mitogen activated protein kinase family members, calcium-calmodulin-dependent protein kinase, and growth factor receptor inhibitors.
  - 2. [CANCELED]
  - 3. [CANCELED]
  - 4. [CANCELED]
- 6. [AMENDED]-The pharmaceutical composition of claim 21, wherein the plant essential oil-compound is eugenol.
- 7. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is thymol.
- 8. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is isoeugenol.
- 9. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is benzyl alcohol.

Attorney Docket No. 45112-045

Application Scrial No. 09/455,543

## **ATTACHMENT**

## "Version With Markings To Show Changes Made."

- 10. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is carvacrol.
- 11. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is cinnamic alcohol.
- 12. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is cinnamic aldehyde.
- 13. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is citronellal.
- 14. [AMENDED]The pharmaceutical composition of claim 21, wherein the plant essential oil compound is trans-anethole.
- 15. [WITHDRAWN] A method for treating cancer, comprising adminstering to a patient in need thereof a therapeutically effective amount of the composition of claim 1.
- 16. [NEW] The pharmaceutical composition of claim 1, wherein the compound is  $\alpha$ -terpineol.